

**PACKAGE LEAFLET**

## PACKAGE LEAFLET

### **Read all of this leaflet**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

### **In this leaflet:**

1. What TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is and what it is used for
2. Before you receive TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG
3. How TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is administered
4. Possible side effects
5. Storing TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG

### **TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG 6,000 units powder and solvent for solution for injection**

#### **Tenecteplase**

- The active substance is tenecteplase. One vial contains 6,000 units of tenecteplase. One pre-filled syringe contains 6 ml of water for injections.
- The other ingredients are L-arginine, phosphoric acid and polysorbate 20.
- The TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG solvent is water for injections.

#### **Marketing Authorisation Holder:**

Boehringer Ingelheim International GmbH  
Binger Strasse 173  
D-55216 Ingelheim am Rhein  
Germany

#### **Manufacturer:**

Boehringer Ingelheim Pharma KG  
Birkendorferstrasse 65  
D-88397 Biberach/Riss  
Germany

### **1. WHAT TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG IS AND WHAT IT IS USED FOR**

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is a powder and solvent for solution for injection. This means that each pack contains:

- one vial of 6,000 units TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG powder and one pre-filled syringe containing 6 ml water for injections

Before use, the solvent (water for injections) is added to the powder to form a solution that is given by injection.

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG belongs to a group of medicines called thrombolytic agents. These medicines help to dissolve blood clots. Tenecteplase is a recombinant fibrin-specific plasminogen activator.

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is used to treat myocardial infarctions (heart attacks) within 6 hours after the onset of symptoms and helps to dissolve the blood clots that have formed in the blood vessels of the heart. This helps to prevent the damage caused by heart attacks and has been shown to save lives.

## **2. BEFORE YOU RECEIVE TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG**

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG will not be prescribed and given by your doctor

- if you have, or have recently had, an illness that increases your risk of bleeding (haemorrhage), including:
  - ❖ a bleeding disorder or tendency to bleed (haemorrhage)
  - ❖ stroke (cerebrovascular event)
  - ❖ very high, uncontrolled blood pressure
  - ❖ a head injury
  - ❖ severe liver disease
  - ❖ a disorder affecting the blood vessels in the eye (e.g. diabetic haemorrhagic retinopathy)
  - ❖ a stomach ulcer (peptic ulcer)
  - ❖ varicose veins in the gullet (oesophageal varices)
  - ❖ abnormality of the blood vessels (e.g. an aneurysm)
  - ❖ certain tumours
  - ❖ inflammation of the lining around the heart (pericarditis); inflammation or infection of the heart valves (endocarditis);
- if you are taking tablets/capsules used to "thin" the blood, such as warfarin or coumarin (anti-coagulants);
- if you have an inflamed pancreas (pancreatitis);
- if you have recently had major surgery including surgery to your brain or spine;
- if you have been given cardiopulmonary resuscitation (chest compressions) for more than 2 minutes duration, in the last two weeks;
- if you are hypersensitive to tenecteplase or any of the other ingredients in TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG.

### **Your doctor will take special care with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:**

- if you have high blood pressure;
- if you have problems with circulation of blood in the brain (cerebrovascular disease);
- if you have had gastrointestinal (gut) or genitourinary bleeding within the last ten days (this may cause blood in stools or urine);
- if you have a heart valve abnormality (e.g. mitral stenosis) with an abnormal heart rhythm (e.g. atrial fibrillation);
- if you have had an intramuscular injection in the last two days;
- if you are aged over 75 years;
- if you weigh less than 60 kg.

### **Pregnancy**

If you are pregnant ask your doctor for advice before you are given TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG.

### **Breast-feeding**

If you are breast-feeding ask your doctor for advice before you are given TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG.

### **Taking other medicines**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

### **3. HOW TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG IS ADMINISTERED**

The doctor calculates your dose of TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG according to your bodyweight, based on the following scheme:

Bodyweight (kg)	less than 60	60 to 70	70 to 80	80 to 90	above 90
Tenecteplase Boehringer Ingelheim Pharma KG (U)	6,000	7,000	8,000	9,000	10,000

Your doctor will give you acetylsalicylic acid and heparin injections in addition to TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG, as soon as possible after your chest pain starts.

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is given by a single injection into a vein by a doctor who is experienced in the use of this type of drug.

Your doctor will give TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG as soon as possible after your chest pain starts as a single dose.

Repetition is not recommended.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG can have side effects.

The following side effects are very common (>10%) with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- low blood pressure (hypotension)
- irregular heart beat
- chest pain (angina pectoris)

The following side effects are common (>1%, <10%) with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- bleeding where the injection is given
- nausea
- vomiting
- fever
- nosebleeds
- further heart attack or chest pain (recurrent ischaemia, reinfarction)
- heart failure
- shock due to heart failure
- inflammation of the lining around the heart (pericarditis)
- fluid in the lungs (pulmonary oedema)
- genitourinary bleeding (you may notice blood in your urine)
- bruising

The following side effects are uncommon ( $>0.1\%$ ,  $<1\%$ ), but have been reported following treatment with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- cardiac arrest
- problem with the heart valve or heart lining (mitral insufficiency, pericardial effusion)
- blood clot in the vein (venous thrombosis)
- fluid between heart lining and the heart (cardiac tamponade)
- rupture in heart muscle
- internal bleeding in the abdomen (retroperitoneal bleeding)
- bleeding in the brain (cerebral haemorrhage)

The following side effects have occurred rarely ( $>0.01\%$ ,  $<0.1\%$ ) after treatment with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- bleeding into the area surrounding the heart (haemopericardium)
- hypersensitivity (anaphylactoid reactions) e.g. rash, hives (urticaria), swelling of the throat
- blood clot in the lung (pulmonary embolism)
- blood clot in the blood vessels

In very rare cases ( $<0.01\%$ ) Tenecteplase Boehringer Ingelheim Pharma KG therapy may lead to crystal cholesterol clots.

Tell your doctor immediately if you think you are experiencing any of these side effects.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. STORING TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG**

Keep out of the reach and sight of children.

Do not store above  $30^{\circ}\text{C}$ . Keep the container in the outer carton in order to protect from light.

Once Tenecteplase Boehringer Ingelheim Pharma KG has been reconstituted it may be stored for up to 24 hours at  $30^{\circ}\text{C}$ . However, for microbiological reasons your doctor will normally use the reconstituted solution for injection immediately.

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG will not be used after the expiry date stated on the label/carton.

## **Further Information**

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

### **België /Belgique/Belgien**

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I-20 139 Milano  
Tel: +39 02 535 51

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### **TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG 8,000 units powder and solvent for solution for injection**

#### Tenecteplase

- The active substance is tenecteplase. One vial contains 8,000 units of tenecteplase. One pre-filled syringe contains 8 ml of water for injections.
- The other ingredients are L-arginine, phosphoric acid and polysorbate 20.
- The TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG solvent is water for injections.

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TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is used to treat myocardial infarctions (heart attacks) within 6 hours after the onset of symptoms and helps to dissolve the blood clots that have formed in the blood vessels of the heart. This helps to prevent the damage caused by heart attacks and has been shown to save lives.

## **2. BEFORE YOU RECEIVE TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG**

**TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG will not be prescribed and given by your doctor**

- if you have, or have recently had, an illness that increases your risk of bleeding (haemorrhage), including:
  - ❖ a bleeding disorder or tendency to bleed (haemorrhage)
  - ❖ stroke (cerebrovascular event)
  - ❖ very high, uncontrolled blood pressure
  - ❖ a head injury
  - ❖ severe liver disease
  - ❖ a disorder affecting the blood vessels in the eye (e.g. diabetic haemorrhagic retinopathy)
  - ❖ a stomach ulcer (peptic ulcer)
  - ❖ varicose veins in the gullet (oesophageal varices)
  - ❖ abnormality of the blood vessels (e.g. an aneurysm)
  - ❖ certain tumours
  - ❖ inflammation of the lining around the heart (pericarditis); inflammation or infection of the heart valves (endocarditis);
- if you are taking tablets/capsules used to "thin" the blood, such as warfarin or coumarin (anti-coagulants);
- if you have an inflamed pancreas (pancreatitis);
- if you have recently had major surgery including surgery to your brain or spine;
- if you have been given cardiopulmonary resuscitation (chest compressions) for more than 2 minutes duration, in the last two weeks;
- if you are hypersensitive to tenecteplase or any of the other ingredients in TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG.

**Your doctor will take special care with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:**

- if you have high blood pressure;
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- if you have a heart valve abnormality (e.g. mitral stenosis) with an abnormal heart rhythm (e.g. atrial fibrillation);
- if you have had an intramuscular injection in the last two days;
- if you are aged over 75 years;
- if you weigh less than 60 kg.

### **Pregnancy**

If you are pregnant ask your doctor for advice before you are given TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG.

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If you are breast-feeding ask your doctor for advice before you are given TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG.



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Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

### **3. HOW TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG IS ADMINISTERED**

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Bodyweight (kg)	less than 60	60 to 70	70 to 80	80 to 90	above 90
Tenecteplase Boehringer Ingelheim Pharma KG (U)	6,000	7,000	8,000	9,000	10,000

Your doctor will give you acetylsalicylic acid and heparin injections in addition to TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG, as soon as possible after your chest pain starts.

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is given by a single injection into a vein by a doctor who is experienced in the use of this type of drug.

Your doctor will give TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG as soon as possible after your chest pain starts as a single dose.

Repetition is not recommended.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG can have side effects.

The following side effects are very common (>10%) with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- low blood pressure (hypotension)
- irregular heart beat
- chest pain (angina pectoris)

The following side effects are common (>1%, <10%) with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- bleeding where the injection is given
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- vomiting
- fever
- nosebleeds
- further heart attack or chest pain (recurrent ischaemia, reinfarction)
- heart failure
- shock due to heart failure
- inflammation of the lining around the heart (pericarditis)
- fluid in the lungs (pulmonary oedema)
- genitourinary bleeding (you may notice blood in your urine)
- bruising

The following side effects are uncommon ( $>0.1\%$ ,  $<1\%$ ), but have been reported following treatment with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- cardiac arrest
- problem with the heart valve or heart lining (mitral insufficiency, pericardial effusion)
- blood clot in the vein (venous thrombosis)
- fluid between heart lining and the heart (cardiac tamponade)
- rupture in heart muscle
- internal bleeding in the abdomen (retroperitoneal bleeding)
- bleeding in the brain (cerebral haemorrhage)

The following side effects have occurred rarely ( $>0.01\%$ ,  $<0.1\%$ ) after treatment with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- bleeding into the area surrounding the heart (haemopericardium)
- hypersensitivity (anaphylactoid reactions) e.g. rash, hives (urticaria), swelling of the throat
- blood clot in the lung (pulmonary embolism)
- blood clot in the blood vessels

In very rare cases ( $<0.01\%$ ) Tenecteplase Boehringer Ingelheim Pharma KG therapy may lead to crystal cholesterol clots.

Tell your doctor immediately if you think you are experiencing any of these side effects.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. STORING TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG**

Keep out of the reach and sight of children.

Do not store above  $30^{\circ}\text{C}$ . Keep the container in the outer carton in order to protect from light.

Once Tenecteplase Boehringer Ingelheim Pharma KG has been reconstituted it may be stored for up to 24 hours at  $30^{\circ}\text{C}$ . However, for microbiological reasons your doctor will normally use the reconstituted solution for injection immediately.

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG will not be used after the expiry date stated on the label/carton.

## **Further Information**

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

### **België /Belgique/Belgien**

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### **TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG 10,000 units powder and solvent for solution for injection**

#### Tenecteplase

- The active substance is tenecteplase. One vial contains 10,000 units of tenecteplase. One pre-filled syringe contains 10 ml of water for injections.
- The other ingredients are L-arginine, phosphoric acid and polysorbate 20.
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#### Manufacturer:

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Germany

### **1. WHAT TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG IS AND WHAT IT IS USED FOR**

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is a powder and solvent for solution for injection. This means that each pack contains:

- one vial of 10,000 units TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG powder and one pre-filled syringe containing 10 ml water for injections.

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clots that have formed in the blood vessels of the heart. This helps to prevent the damage caused by heart attacks and has been shown to save lives.

## **2. BEFORE YOU RECEIVE TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG**

**TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG will not be prescribed and given by your doctor**

- if you have, or have recently had, an illness that increases your risk of bleeding (haemorrhage), including:
  - ❖ a bleeding disorder or tendency to bleed (haemorrhage)
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  - ❖ a disorder affecting the blood vessels in the eye (e.g. diabetic haemorrhagic retinopathy)
  - ❖ a stomach ulcer (peptic ulcer)
  - ❖ varicose veins in the gullet (oesophageal varices)
  - ❖ abnormality of the blood vessels (e.g. an aneurysm)
  - ❖ certain tumours
  - ❖ inflammation of the lining around the heart (pericarditis); inflammation or infection of the heart valves (endocarditis);
- if you are taking tablets/capsules used to "thin" the blood, such as warfarin or coumarin (anti-coagulants);
- if you have an inflamed pancreas (pancreatitis);
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- if you have had an intramuscular injection in the last two days;
- if you are aged over 75 years;
- if you weigh less than 60 kg.

### **Pregnancy**

If you are pregnant ask your doctor for advice before you are given TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG.

### **Breast-feeding**

If you are breast-feeding ask your doctor for advice before you are given TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG.

### **Taking other medicines**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

### **3. HOW TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG IS ADMINISTERED**

The doctor calculates your dose of TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG according to your bodyweight, based on the following scheme:

Bodyweight (kg)	less than 60	60 to 70	70 to 80	80 to 90	above 90
Tenecteplase Boehringer Ingelheim Pharma KG (U)	6,000	7,000	8,000	9,000	10,000

Your doctor will give you acetylsalicylic acid and heparin injections in addition to TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG, as soon as possible after your chest pain starts.

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG is given by a single injection into a vein by a doctor who is experienced in the use of this type of drug.

Your doctor will give TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG as soon as possible after your chest pain starts as a single dose.

Repetition is not recommended.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG can have side effects.

The following side effects are very common (>10%) with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- low blood pressure (hypotension)
- irregular heart beat
- chest pain (angina pectoris)

The following side effects are common (>1%, <10%) with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- bleeding where the injection is given
- nausea
- vomiting
- fever
- nosebleeds
- further heart attack or chest pain (recurrent ischaemia, reinfarction)
- heart failure
- shock due to heart failure
- inflammation of the lining around the heart (pericarditis)
- fluid in the lungs (pulmonary oedema)
- genitourinary bleeding (you may notice blood in your urine)
- bruising

The following side effects are uncommon ( $>0.1\%$ ,  $<1\%$ ), but have been reported following treatment with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- cardiac arrest
- problem with the heart valve or heart lining (mitral insufficiency, pericardial effusion)
- blood clot in the vein (venous thrombosis)
- fluid between heart lining and the heart (cardiac tamponade)
- rupture in heart muscle
- internal bleeding in the abdomen (retroperitoneal bleeding)
- bleeding in the brain (cerebral haemorrhage)

The following side effects have occurred rarely ( $>0.01\%$ ,  $<0.1\%$ ) after treatment with TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG:

- bleeding into the area surrounding the heart (haemopericardium)
- hypersensitivity (anaphylactoid reactions) e.g. rash, hives (urticaria), swelling of the throat
- blood clot in the lung (pulmonary embolism)
- blood clot in the blood vessels

In very rare cases ( $<0.01\%$ ) Tenecteplase Boehringer Ingelheim Pharma KG therapy may lead to crystal cholesterol clots.

Tell your doctor immediately if you think you are experiencing any of these side effects.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. STORING TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG**

Keep out of the reach and sight of children.

Do not store above  $30^{\circ}\text{C}$ . Keep the container in the outer carton in order to protect from light.

Once Tenecteplase Boehringer Ingelheim Pharma KG has been reconstituted it may be stored for up to 24 hours at  $30^{\circ}\text{C}$ . However, for microbiological reasons your doctor will normally use the reconstituted solution for injection immediately.

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA KG will not be used after the expiry date stated on the label/carton.

## **Further Information**

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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**This leaflet was last approved on**